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UNIT

**EFFECT OF COLD CHAIN MANAGEMENT PRACTICES ON AVAILABILITY OF VACCINE
IN PRIVATE HEALTH FACILITIES IN ADDIS ABABA CITY ADMINISTRATION**

By

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ADMINISTRATION**

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I, Benti Firomsa, declares that this thesis work entitled “**The effect of cold chain management practices on availability of vaccine in private health facilities in Addis Ababa City Administration**” is my original work in partial fulfillment of the requirement for the award of Degree of Masters’ of Art in Logistics and Supply Chain Management. I also declare that it has never been presented in this or any other university and that all resources and materials used in the thesis have been duly acknowledged.

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This thesis entitled as **the effect of cold chain management practices on availability of vaccine in private health facilities in Addis Ababa City Administration** has been submitted for examination with my approval as a university advisor. In my opinion, this thesis is suitable for submission in partial fulfillment of the requirements for the award of Degree of Masters' of Art in Logistics and Supply Chain Management.

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The researcher

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Acronyms

AACHB-Addis Ababa City Health Bureau

BCG-Bacillus Calmette-Guerin

CDC- Centres for Disease Control and Prevention

DPT-Diphtheria-Pertussis-Tetanus Vaccine

EPI-Expanded program on Immunization

FMOH-Federal Ministry of Health

Hib- Haemophilus Influenza Type B

IPV-Inactivated Poliovirus

ISCL- Immunization Supply Chain and Logistics

OPV-Oral Poliovirus

PCV-Pneumococcal Conjugated Vaccine

PFSA-Pharmaceutical Fund and Supply Agency

TT-Tetanus Toxoid

WHO-World Health Organization

Abstract

The availability of vaccine is very important to provide vaccination service. Vaccine supply chain requires Cold chains which are widely used to ensure the viability of products in the vaccine management, and are critical components of vaccination programs. But with few exceptions, vaccine supply and logistics systems around the world are unable to keep pace with growing immunization programs. Reportedly, there have been challenges in major components of vaccine supply chain which are storage system, distribution system, technical Capacity, and management procedures. Those challenges affect the availability of vaccine while interruption of availability of vaccine significantly affects provision of immunization service as EPI is fully product dependent. It was therefore important to assess the effect of cold chain management practice on availability of vaccine. The study was conducted on private health facilities in Addis Ababa city administration providing vaccination service by using Cross sectional survey design. The population of the study was vaccination focal persons at private health facilities providing EPI services in Addis Ababa City Administration. The sample was determined by using single population proportion formula for cross sectional study and was calculated to be 47 and then data was collected through self-administered questionnaire from sampled facilities' vaccination focal person who is responsible to manage vaccine with 91.5% response rate. The questionnaire was coded and analyzed using SPSS-V-20. Descriptive statistics and correlation analysis were undertaken to grossly understand about the collected data and nature of the study variables. Furthermore, regression analysis was conducted to assess effect of independent variables as storage system, distribution system, technical Capacity and information system on the dependent variable as availability of Vaccine. It has been revealed from the analysis thus that only the Storage System and Information System have significant positive effect on availability of vaccine. Hence, health sector management at different level and other stakeholders should provide attention to improving storage practice and upgrading information system.

Key Words: Challenges of cold chain management, availability of vaccine

CHAPTER ONE: INTRODUCTION

This chapter deals with back ground of the study, statement of the problem, research hypothesis, objective of the study, significance of the study, scope of the study and organization of the study.

1.1. Background of the study

Currently, Vaccine-preventable disease levels are at near record low. This was not the case at the beginning of the 20th century, when infectious diseases were the greatest threat to public health and the leading cause of death in the United States and elsewhere. During that period, few effective treatments or measures were available for preventing large numbers of deaths from these diseases, despite the fact that in 1796, Edward Jenner performed the Western World's first vaccination. During the 20th century, the Golden age of vaccines witnessed the development and acceptance of vaccines for diphtheria (discovered in 1921, but not used widely until the 1930s), polio vaccine with inactive virus (1955) and live attenuated virus (1961), measles (1963), and combination measles-mumps-rubella (MMR) vaccine (1971). Estimates indicate that these vaccines have prevented more than 3 million deaths per year worldwide from infectious diseases. These products are biologicals and needs cold chain management to maintain potency (Jagannath M., et al, 2009).

The vaccine cold chain is a temperature controlled environment used to maintain and distribute vaccines in optimal condition. A proper cold chain is a temperature controlled supply chain that includes all equipment and procedures used in transport and storage and handling of vaccines from time of manufacture to administration of vaccine (CDC, 2014). According to World Health Organization (WHO) cold chain is a system of storing and transporting vaccine at recommended temperature range from the point of manufacture to point of use (immunization & biologicals, 2004). The cold chain relies on three main elements well-trained personnel, reliable transportation and storage equipment and efficient management procedures. The cold chain begins with the cold storage unit at manufacturing plant, extends through transport of vaccine to the distributor, then delivery and storage at the provider facility, and ends with administration of

vaccine to the patient. Appropriate storage conditions must be maintained at every link in the cold chain (CDC, 2014).

Vaccination has been shown to be one of the most cost-effective health interventions worldwide, through which a number of serious childhood diseases have been successfully prevented or eradicated. To maintain vaccines perfectly conserved from its manufacture through administration requires an adequate cold chain infrastructure, compliance to standards and effective management. At the end of the chain, primary health care providers must have adequate knowledge to manage the cold chain (Henjeet K., et al, 1996).

To improve vaccine management, the World Health organization (WHO) has created a set of practice guidelines for different service levels, which include immunization techniques, vaccine monitoring, cold chain management and reporting systems(WHO, 2004). The cold chain guidelines recommend: the vaccine storage in remote sites should be maintained in the temperature range of 2-8°C, the use of minimum/maximum thermometers, temperature charts and the shake test (Galazka A., et al, 1998). However, these guidelines are often practically quite difficult to implement in field situations due to various factors like infrastructure problems and work load pressures (Berhane Y., Demissie M., 2000).

The immunization supply chain and logistics (ISCL) systems, which were designed in the 1980s, have supported the achievement of acceptable vaccination coverage, using coping mechanisms to overcome enduring challenges in vaccine storage, distribution and management. The dedication, intelligence and creativity of health workers acting within outdated immunization and logistics system have substituted for much needed assets and capital. Despite many efforts, national immunization programs, already struggling to meet the demands routine immunization and supplemental campaigns, may not be in the best position to respond to be the introduction of all the new vaccines (WHO, 2014c). To be effective, however, a number of elements in vaccination program need to be implemented properly, including cold chain management, vaccine management, logistic management and waste management. Failure to properly implement these can reduce the level of protection that is expected from a vaccination program (WHO, 2008). A widening variety of new vaccines and immunization schedules, a diversity of service delivery strategies, an expanding target population, increased cold chain infrastructure requirements and insufficient funding, are just a few of new realities that will further stress immunization supply chain and logistics (ISCL) systems, which were initially designed to manage fewer, less

expensive and less bulky vaccines and related supplies. Existing systems cannot keep pace with the changing landscape of national immunization programmes, resulting in stock-outs, potential administration of ineffective vaccines, avoidable wastage and inadequate cold chain capacity, all of which have considerable coverage, performance and, cost implications. These inefficiency not only hinder the ability to provide much needed immunizations, they also yield a lower return in health outcomes for those investing in research, production, procurement and delivery of vaccines, threatening the dependability of future funding sources. Therefore, the availability of a proper cold chain and vaccine and logistics management system from the vaccine manufacturer to the end user, and follow-up after the vaccination program is finished must be ensured. Without vaccines as well as safe and effective distribution systems and delivery practices, disease would become more rampant and the public health and the community would be overburdened with treatment costs and deaths particularly in children.

The aim of this study is to examine the effect of cold chain management practices on availability of vaccines in private health facilities managing vaccine in Addis Ababa city administration.

1.2. Statement of the problem

The importance of cold chain management is crystal clear in vaccine Supply chain. But there are major challenges facing lower and middle income countries in storage, distribution, technical capacity and information system in cold chain management practices. Those challenges lead to miss the goal of cold chain management. By definition a cold chain is a monitored temperature controlled supply chain (kohli P., 2008). The goal of the cold chain is to keep a sample or material within a certain temperature range during all stages of delivery, processing and storage. Cold chains are widely used to ensure the viability of products in the Pharmaceuticals, and are critical components of vaccination programs (David W., 2013). The success of the EPI is therefore highly sensitive to the cold chain status and hence its management should not be taken lightly as there are significant challenges in cold chain management practices. Studies conducted at different areas also confirmed those challenges.

Vaccine freezing occurred at all levels of the cold chain, especially from the district warehouse to health centers (Ministry of Public Health, 2009). With few exceptions, vaccine supply and logistics systems around the world are unable to keep pace with growing immunization programs

(WHO, 2014a). According to WHO less than 25% of countries are operating at even a minimum standard within the criteria of maintenance, stock management and distribution. On the top of this, only 29% of the countries are meeting minimum standards for temperature control. A study done in Papua New Guinea recorded that vaccine temperatures during transportation from the national warehouse to health centers and detected frozen vaccine vials caused by insulation between the vaccines and the icepacks that were not sufficient to protect the vaccines from direct contact with the icepacks. During a three-day monitoring period, a study in New South Wales used data loggers to measure the temperature of 53 vaccine refrigerators in pharmacies and found that only 19% of the refrigerators studied had temperatures that fell within the acceptable range, while 23% of the refrigerators had temperatures that fell to less than 0°C and 29% had temperatures higher than 8°C (Population Report, 1986)).

The World Health Organization (WHO) has stated that as much as 25% of all vaccine products reach their destination in a degraded state. The Medicines and Healthcare Products Regulatory Agency reports that temperature rises above desired parameters are the number one critical deficiency in pharmaceutical warehouses contributing to about 43% of reported non-compliant cases (Jet Environmental, 2009). It is not the general conditions that affect product quality, but extremes of temperature within the operational space. As global warming is widely accepted as reality, temperature control issues are likely to become even more of a problem in warehouses that are not equipped with appropriate cooling systems.

Based on the estimated total cost of vaccine per fully immunized child in a developing country, Ethiopia is investing about \$136.8 million USD (3 billion ETB) annually and this cost is allocated both by partners and the government of Ethiopia each year. This huge amount of money for procurement of vaccines will be expected to be ultimately covered by the government of Ethiopia in long run (FMOH, 2015a). Despite huge vaccine costs to vaccinate more than three million cohorts of children annually, there is no vaccine wastage monitoring system in place and thus the vaccine wastage for the vaccines in the EPI program is unknown. A vaccine wastage even as small as 5% corresponds to a loss of 150,447,00 birr annually in Ethiopia for the current vaccines and it will increase as more expensive vaccines are introduced into the EPI program. Therefore, proper cold chain and vaccine management is important to reduce the high cost of

vaccine wastage and ensure that children are vaccinated with safe and potent vaccines at reasonable cost (FMOH, 2015b).

It is estimated that more than 32% of counted available refrigerators and freezers are not functional and more than 90% of the cold chain equipment are no-optimal, potentially exposing vaccines to excessive heat or freezing. The 2013 cold chain equipment inventory (2013) result described the cold chain system in Ethiopia to be one of the bottlenecks for achieving routine immunization program objective (to reach every child with a potent and safe vaccine within a reasonable distance)(National cold chain equipment inventory, 2013). Although there are a number of studies with regard to cold chain management most of them focus public health facilities. There is no study conducted in Ethiopia to assess such practice on private facilities and it is important to conduct study to see effect of cold chain management on vaccine availability on private facility to bridge this gap. Hence, this research will assess the effect of cold chain management practice in private facilities managing vaccine in Addis Ababa to analyze its effect on availability of vaccine at private service delivery level (FMOH, 2013b).

1.3. Objective of the study

1.3.1. General objective

The general objective of the research is to assess the effect of cold chain management practices on the availability of vaccines in private facilities in Addis Ababa City Administration

1.3.2. Specific objectives

The specific objectives of the study are

- To assess the effect of storage system on availability of vaccines in private health facilities in Addis Ababa City Administration
- To assess the effect of distribution system on availability of vaccines in private health facilities in Addis Ababa City Administration
- To assess the effect of technical capacity on availability of vaccines in private facilities in Addis Ababa City Administration
- To assess the effect of information system on availability of vaccines in private health facilities in Addis Ababa City Administration

1.4. Hypotheses of the study

In order to answer the research question of the study, the researcher identified the following hypotheses:

- Null Hypothesis 1: Storage system has no a significantly positive effect on availability of vaccine in the private health facilities providing immunization service in Addis Ababa City Administration.
- Alternative Hypothesis 1: Storage system has a significantly positive effect on availability of vaccine in the private health facilities providing immunization service in Addis Ababa City Administration.
- Null Hypothesis 2: Distribution system has no a significantly positive effect on availability of vaccine in private health facilities providing immunization service in Addis Ababa City Administration.
- Alternative Hypothesis 2: Distribution system has a significantly positive effect on availability of vaccine in private health facilities providing immunization service in Addis Ababa City Administration.
- Null Hypothesis 3: Technical capacity has no a significantly positive effect on availability of vaccine in private health facilities providing immunization service in Addis Ababa City Administration.
- Alternative Hypothesis 3: Technical capacity has a significantly positive effect on availability of vaccine in private health facilities providing immunization service in Addis Ababa City Administration.
- Null Hypothesis 4: Information system has no a significantly positive effect on availability of vaccine in the private health facilities in Addis Ababa City Administration.
- Alternative Hypothesis 4: Information system has a significantly positive effect on availability of vaccine in the private health facilities in Addis Ababa City Administration.

1.5. Significance of the study

This study provides use full evidence on effect of cold chain management practice on the availability of vaccine on private facilities. Hence, helps all stake holders in this area including policy makers, international organization working on immunization, regulatory authorities, health care providers, EPI coordinators and donors in guideline development and implementation, compliance with minimum standard, in providing technical and financial support on private health facilities. Policy makers and regulatory authorities utilize this research finding in guideline development/revision in terms of infrastructure, product and human resource to manage vaccine products at private health facility and to provide important support and follow up of the implementation of policy requirement at those facilities. Health sector can get important information on strengthen and weakness of private facilities on cold chain management in providing tailored technical and financial support at private facilities with this regard. It also help to academician for further investigation and can be a source of literature specifically in bridging literature gap in studies involving private facilities.

1.6. Scope of the study

This study is limited to private health facilities managing vaccine in Addis Ababa City Administration. The study addresses effect of cold chain management practices in terms of technical capacity, information system, storage and distribution of private facilities managing vaccine in Addis Ababa City Administration. It does not touch the issue from RHB, FMOH and PFSA perspective.

1.7. Limitation of the study

The researcher used cross sectional study to collect information with in limited time and utilized self-administered questionnaire. Hence, subjected to time limitation and have no chance to clarify each question for respondent which would improve the quality response unlike interview. But data collection team used to review the filled tool to minimize data quality problem arising from such issues.

1.8. Organization of the study

This study will be organized in to five chapters. The first chapter including back ground of the Study, Statement of problem, Objectives of the study, scope of the study, limitation of the study and paper organization. The second chapter presents review of related literature and the third presents research methodology. The forth chapter will deal with data presentation, discussion and interpretation and the fifth chapter will deal with summary, conclusion and recommendation.

CHAPTER TWO- RELATED LITERATURE REVIEW

This chapter reviews relevant literature on the key areas that the study covers. It presents related theoretical literature with a focus of on the objectives and theoretical thresholds of this study. It also reviews related empirical literature, conceptual frame work and literature gap.

2.1. Theoretical literature

2.1.1. Cold chain management system

The Immunization Supply Chain and Logistics (ISCL) systems designed in the 1980s have supported the achievement of acceptable vaccination coverage using coping mechanisms to overcome enduring challenges in vaccine storage, distribution, and management (*WHO, 2014*)

The cold chain system is a means for storing and transporting vaccines in a potent state from the manufacturer to the person being immunized (*WHO, 2014*). It consists of a series of storage and transport links, all designed to keep vaccines within an acceptable temperature range until it reaches the users. It makes use of human, material and financial resources as well as standards at different levels. The cold chain remains a highly vulnerable point for national immunization programs in developing countries with tropical climates (*WHO, 1998*).

Cold chains are common in the food and Pharmaceutical industries and also in some chemical shipments. Many biological substances deteriorate when exposed to heat, sunlight, or fluorescent light. When transporting and storing such biological substances, it is imperative to control environmental conditions, ensuring that exposure to potentially damaging environmental factors is minimized. One common temperature range for a cold chain in Pharmaceutical industries is 2 to 8 degree Celsius. But the specific also the recommended temperature ranges by WHO for the cold chain system of transporting and storing vaccines (*health council, 2008*).

The cold chain has three main components: transport and storage equipment, trained personnel, and efficient management procedures. All three elements must combine to ensure safe vaccine transport and storage. The cold chain begins from the cold storage unit in the vaccine manufacturing plant, extends through transfer of vaccine to the distributor and then to the provider's office, and ends with the administration of the vaccine to the patient. Excess heat or cold will reduce their potency, increasing the risk that recipients will not be protected against

vaccine preventable diseases. To ensure the optimal potency of vaccines, careful attention is needed in handling practices at all levels of the cold chain (Afsar A., Kartoglu U., 2006).

2.1.2. Reliability of cold chain management and vaccine availability

The presentation and formulation of vaccines determines the storage requirement, maximum storage time at primary and sub national level, type of cold chain equipment used during storage and transportation at all level of the vaccine supply system. The temperature (and time at temperature) tolerances depend on the actual product. Each vaccine has its own specific storage requirements so it is extremely important to know how long, and at what temperature, each vaccine can be stored. Most vaccines can be stored at positive temperature (between +2 and +8 degree Celsius. However, only some vaccines can be stored at negative temperature (between -15 and -25 degree Celsius) (WHO, 2008). In Ethiopia there are vaccines which required two different temperature range storage requirements at national, regional and zonal level. A negative storage temperature is required (-15 to 25 °C) to store OPV vaccines and a positive temperature required (2-8 °C) for BCG, TT, Measles, Penta, PCV, Rota, IPV at national, regional and zonal level. The maximum recommended storage period at national, regional and zonal level is six and three months respectively. All vaccines and diluents in health facilities should be stored in a temperature range of 2-8 °C for a maximum of one month period (FMOH, 2015b).

2.1.3. Sensitivity to heat and freezing

Vaccines are sensitive biological products. Vaccine potency, meaning its ability to adequately protect the vaccinated patient, can diminish when the vaccine is exposed to inappropriate temperatures. Once lost, vaccine potency cannot be regained. Based on the relative heat sensitivity vaccines can be categorized in to six, arranged in alphabetical order, not in order of sensitivity to heat within the group. The most heat sensitive vaccines are in group A and the least heat sensitive vaccines are in group F. For example, Oral poliovirus, influenza, inactivated poliovirus, cholera, bacillus calmette-guerin, hepatitis B are group A, B, C, D, E and F respectively(WHO, 2008). Freezing is also the most common reason for vaccine damage. Freezing of vaccine refers to situation whereby vaccines stored at or below 0 °C of temperature for types of vaccines which need to be stored in refrigerator temperature range of +2 °C and +8 °C. Vaccine damage at temperature of 0 °C is common although it may not appear frozen

(Commonwealth of Australia, 2013). For example, a study done In Nigeria, the potency of oral polio vaccine (OPV) as well as vaccines for measles and yellow fever was found to decrease below international standards when they were transported from the national warehouse to health facilities. The rate of the decrease in the potency of measles vaccine was greater than in OPV and yellow fever vaccine. The potency loss was most likely due to several factors, including repeated cycles of vaccine freezing and thawing caused by deficiencies in cold storage equipment, inconsistent electrical distribution systems, a lack of backup electricity, and improper vaccine storage (*Acu F., et al, 1996*).

2.1.4. Sensitivity to light

Some vaccines are very sensitive to light and lose potency when exposed to it. Such vaccines should always be protected against sunlight or any strong artificial light, and exposure should be minimized. Vaccines that are as sensitive to light as they are to heat include BCG, measles, measles-rubella, measles-mumps-rubella and rubella. These vaccines are often supplied in dark glass vials that give them some protection from light damage; but they should be kept in their secondary packaging for as long as possible to protect them during storage and transportation (WHO, 2005). Vaccines and cold chain equipment should be placed in such a way in the room that they are not exposed to sunlight any time during the day. Exposure to sun light will lead to increase in core temperature of the cold chain equipment, which would break the cold chain by causing an increase in the temperature of the vaccines (Naik A., Rupani M., & Bansal R., 2013).

2.1.5. Cold chain equipment and its use

There are different vaccine storage conditions appropriate to each level of the cold chain. Thus, each level requires different storage equipment depending on the quantity of vaccine to be stored, the duration of storage and the temperature necessary. All equipment must be able to keep vaccines safely whatever the outside temperature, and however the climate varies at different times of the year. There are also different types of equipment designed for transporting vaccines between the various levels of the cold chain, and for use during immunization sessions. Cold chain equipment requires installation and maintenance, which necessitates the availability of properly trained technicians, replacement parts, a system to monitor equipment performance, and the capability to rapidly respond to breakdowns and failures. Although existing supply

chains should already have maintenance plans in place, recent cold chain assessments reveal consistent deficiencies in this area (PATH, 2008). Developing, procuring, supplying, and maintaining shipment and storage materials, including appropriate vehicles, refrigerators, and cold boxes, is an ongoing challenge.

2.2. Empirical literature

2.2.1: Cold chain management practice

A cold chain is a temperature-controlled supply chain. An unbroken cold chain is uninterrupted series of storage and distribution activities which maintain a given temperature range. Despite strict requirements to monitor temperature to keep vaccine in allowed range vaccines are usually subjected to temperature out of the range. A Study in the United States indicated that only 2 of the 21 clinics studied had refrigerator temperatures that fell within the acceptable range. About 63% of the samples had temperatures that fell below the acceptable range, 59% reached temperatures higher than the acceptable range, and 93% were both higher and lower than the acceptable range (*Froes P.,1995*). A study in Bolivia revealed that temperature of vaccine throughout its transportation from the national warehouse to 11 communities in 3 provinces reported that the proportion of time that the temperature fell to less than 0°C ranged from 2% to 50%. Vaccine freezing occurred at all levels of the cold chain, especially from the district warehouse to health centers. In addition, 7 of the 11 routes from provincial to district warehouses had a temperature higher than 8°C (*Nelson C., et al, 2007*).

Weaknesses in the cold chain were observed both during transportation and storage of the vaccines. Some factors contributing to weaknesses of the cold chain were delays during transportation, quality of refrigerators, method of storage, too long storage at the health unit, improper use of refrigerators, power interruption, equipment breakage, and lack of trained personnel capable of managing the cold chain (*Lugosi L., Battersby A., 1990*).

A study done in central Ethiopia revealed that of 116 visited facilities, only 22 (19%) had functional refrigerators. The remaining facilities transported vaccines from nearby facilities having functional refrigerators. Complete temperature recording of the last month was observed in 13(59.1%) facilities. Of 22 functional fridges, the thermometer reading was found to be

outside the recommended range in 6(27.3%) on the date of data collection. Vaccine storage in the refrigerator was not proper in 12(54.5%) facilities. Sixty-five (56%) health workers had satisfactory knowledge on cold chain management. Professional qualification and year of service in the immunization program showed a statistically significant association with knowledge of cold chain management ($P<0.05$) (Rogie B., Berehane Y.,2012).

The study in Ethiopia showed that there is a real danger of vaccines losing their potency at these centers even if they were potent on arrival. The conditions of the cold chain system were described based on 64 health centers of these complete temperature record was observed in 37(57.8%) of the centers. Thermometer was not available in four (6.3%) and thermometer reading was found to be outside the optimal range in another seven (10.9%) centers. Vaccine storage in the refrigerator was not proper in 47 (73.4%) centers. Majority of the centers had neither trained personnel nor budget for maintenance of the cold chain (Berhane Y., Demissie M., 2000).

2.2.2. Challenges in cold chain management practice

Now a day there are number of vaccines available and inventions of new vaccines have generated serious challenges in their vaccine supply and logistic systems. Storage capacity bottlenecks and system inefficiencies threatens the access, availability and quality of vaccines. People who have been involved in vaccine supply chains over the years generally agree that the following are the major challenges facing lower and middle income countries (Kaufmann J., et al, 2011).

2.2.2.1 Vaccine storage and distribution

Development of effective vaccines has reduced the incidence of many serious infectious diseases. However, the efficacy of vaccines can be compromised by fault transport, storage and handling. In the 1970s and again in the early 1990s, improper vaccine storage and handling were cited as possible reasons for vaccine failure that resulted in measles outbreaks in Canada (as cited by Lilian Y, 1995). Stock outs of vaccines and related supplies are quite common at the regional, district and health center levels because of a poor vaccine distribution system and inadequate stock management. While a regular vaccine distribution schedule exists on paper, in

practice deliveries are erratic and depend on the availability of appropriate transport, which is often lacking (global vaccine action plan, 2016). At the local level, a 2015 cold chain inventory found that while 85% of health centers had refrigerators, only 72% of them were functioning and thus only 62% of health centers could store vaccines. This means that they must collect vaccine from the district stores or from another health center on day of immunization sessions and are dependent transportation being available (global vaccine action plan, 2016).

2.2.2.2 Technical capacity

Training supply chain personnel is usually focused narrowly on specific activities, such as storekeeping, maintaining cold-chain records, and providing security for commodities, rather than the higher order planning, analysis, and performance management skills needed by supply chain managers. Studies done in different countries show that inadequate knowledge and practices exist regarding cold chain management in primary health care facilities (de Timteo M., 2007). Those who manage the supply chain must be given higher status and a seat at the planning table, so managers can advise on logistical road blocks and how to overcome them. People involved in transportation and supply of vaccines need to be constrained and have knowledge of cold chain and how to handle breakage of cold chain. Without the pre-requisite knowledge of how to handle vaccines being transported can seriously affect the vaccine potency which in turn can result in wastage of vaccines and thus, increase in price.

2.2.2.3 Information system

Many countries do not have reliable data about past vaccine usage or accurate projections of target population and their locations. National vaccine forecasting is done using population estimates, birth rates, infant mortality rates, vaccine waste rates, and prior year estimates of usage (Kaufmann J., et al, 2011). Because census data are typically only brought up to date every 10 years, even in the best organized developing countries, the combination of inaccurate estimates means that incorrect vaccine forecasts are replicated year after year. Unnecessary in-country logistical burdens and expense are the result when too much or too little vaccine is ordered as a result of the inaccuracies. Inaccurate or outdated census counts, population migrations, and unforeseen changes in birth rates all contribute to the problem. Local health managers may try to counteract these by head counts but they introduce their own biases,

including inflation of numbers to ensure adequate amounts of vaccines and deflation to make coverage rates look high (FMOH, 2013)

There is considerable lack of coordination between those people and Organizations that finance and procure vaccines for shipment to developing countries and those supply chain managers and storekeepers responsible for receiving and distributing the shipments. Financing and procurement stakeholders have limited knowledge of the constraints faced by vaccine officials in developing countries. Supply chain planners and managers are rarely consulted or involved in the plans that ultimately produce incoming vaccine shipments (Kaufmann J., et al, 2011)

2.2.3. Global perspective on vaccine management

The study conducted in Bali province Indonesia regarding improving the animal health cold chain and vaccine management indicated that there were urgent needs for improvements in management of vaccine. Approximately half of the refrigerators were unsuitable for vaccine storage generally in poor condition, temperature was not monitored. As a result healthcare workers did not know if the temperature of refrigerator was within the recommended range at 2-8 °C. In addition vaccines were arranged inappropriately in the refrigerators, and were mixed with other items including expired and partially used vaccine vials (Vogel., et al, 2011).

In a cross sectional study that was conducted in Toronto Canada from August to December 1992, staff responsible for vaccine storage were interviewed about their knowledge and practices of vaccine handling and storage. Refrigerators were inspected, fewer than 7 (6%) practices staff answered all questions related to vaccines storage and handling correctly, and only 11(10%) refrigerator had thermometer. One-third of refrigerators had temperatures outside the recommended range of 2 to 8 °C. Older refrigerators were more likely to had inappropriate temperature than newer ones. Knowledge and practice of vaccine storage and handling were often inadequate in primary care Physicians office (Yuan L., 1995).

The study conducted in Secunderabad India concerning vaccine distribution round that the implementation of an immunization program in the rural areas was affected by gap in the distribution system. The study also identified other problem areas such as a faulty cold chain and need for an improved monitoring and control system and for better supervision (Subramanyam K., 1989).

2.2.4. Ethiopian perspective on vaccine management

The Federal Democratic Republic of Ethiopia is the second most populous country in sub-Saharan Africa with an estimated population of approximately 92.08 million people and the tenth largest by area with its 1.1 million square kilometers. The health service currently reaches over 93% of the population. The Federal Ministry of Health has been working to ensure an efficient and high performing healthcare supply chain that will ensure equitable access to affordable medicines for all Ethiopians. In past years, significant progress has been made, although various challenges remain an inadequate supply of quality and affordable essential Pharmaceuticals, poor storage conditions and weak stock management resulted in high levels of waste and stock outs. Democratization and decentralization of the health service has brought an opportunity for the EPI programme as the implementing bodies (woredas) are becoming more capable both administratively and economically to play a role in resource mobilization and allocation for immunization programmes in their respective areas. Some regions and woredas have already started allocating budgets for operational costs, and a few have started contributing for capital costs by procuring refrigerators. This financial contribution and commitment at every structure has shown primary ownership and responsibility for establishing good governance and for providing effective and quality immunization services. However, contributions for purchase of vaccines and injection materials by the regions and woredas have yet to be started (FMOH, 2015a).

The expanded programme on immunization was launched in 1980 with the objective of increasing the coverage by 10% annually. However, the coverage in the first 20 years was very low although during the 1990's good progress was observed through Universal Child Immunization (UCI). The reaching every district (RED) approach has been implemented in Ethiopia since 2004 in districts with poor immunization coverage and high dropout rates. As a result, the coverage showed marked improvement. DPT3 coverage increased from 52% in 2003 to 87% in 2014. The variation in coverage among regions, however, is large. Now, the Reaching every district strategic approach is recast to reaching every children/ community strategic approach in order to deal with inequities within districts. Immunization services are being rendered in most of the health facilities and in outreach and mobile services for the community residing beyond 5km from the static health facilities. In the routine EPI program the traditional

six antigens are being given in both the public and private services. Starting in 2007, pentavalent formulation, DPT-HepB-Hib was introduced into the routine immunization program thus increasing the number of total antigens given to infants to eight (DPT-HepB-HIB, BCG, OPV and measles). In addition, penta valent pneumococcal vaccine was introduced in the October 2011 and increased the total number of antigens in the routine immunization programme to nine, Rota (FMOH, 2013).

2.3- Literature gap

Every year millions of people are vaccinated preventively. Preventive vaccination takes place before a disease emerges and aims at preventing a disease outbreak. Besides preventive vaccination, reactive vaccination can take place during an outbreak of an infectious disease or in response to a bioterror attack. Although vaccination is a medical intervention, successful vaccination campaigns are impossible without good logistics. The importance of vaccine logistics is demonstrated by the growing number of studies on the subject. There are a number of empirical literature involving storage system, Distribution system, Technical Capacity and Information System both globally and in Ethiopia from different perspective. But this issue is neglected with regard to private health facilities in Ethiopia. As far as the researcher search is concerned there is no study on this issue regarding private health facilities. Hence this paper would help to bridge literature gap in this area.

2.4. Conceptual framework

There is association between vaccine cold chain management and availability of vaccine. The safety of cold chain Pharmaceuticals/ Vaccines is greatly influenced by variation during transport, storage conditions, handling and packaging (Bishara R.H., 2007). WHO recommends the range of temperature for storing and transporting vaccine should be on the basis of data supplied by manufacturer. Each vaccine has its own specific storage requirements so it is extremely important to know how long, and at what temperature each vaccine should be handled as they are delicate biological substances that can become less effective or destroyed if they are not stored and transported properly. The cold chain has three main components: transport and storage equipment, trained personnel, and efficient management procedures. All three elements must combine to ensure safe vaccine transport and storage (Afsar A. & Kartoglu U., 2006).

Now a day there are number of vaccines available and inventions of new vaccines. But there are serious challenges regarding the main components of cold chain that eventually affect availability of vaccine and then immunization program. Storage capacity bottlenecks and system inefficiencies threatens the access, availability and quality of vaccines. People who have been involved in vaccine supply chains over the years generally agree that the storage, the distribution, the technical capacity and information system are the major challenges facing lower and middle income countries (Kaufmann J., et al, 2011).

The operation of the pharmaceutical cold chain management cycle is also affected by some intervening factors which are political, legal, and regulatory framework may cause delays in reducing on the lead time and compromise on product quality and safety, however these intervening factors were not measured in this study.

Based on the above explanation the following conceptual frame work was adopted from (Njuguma M.W., Mairura C.J., and Ombui K., 2015)

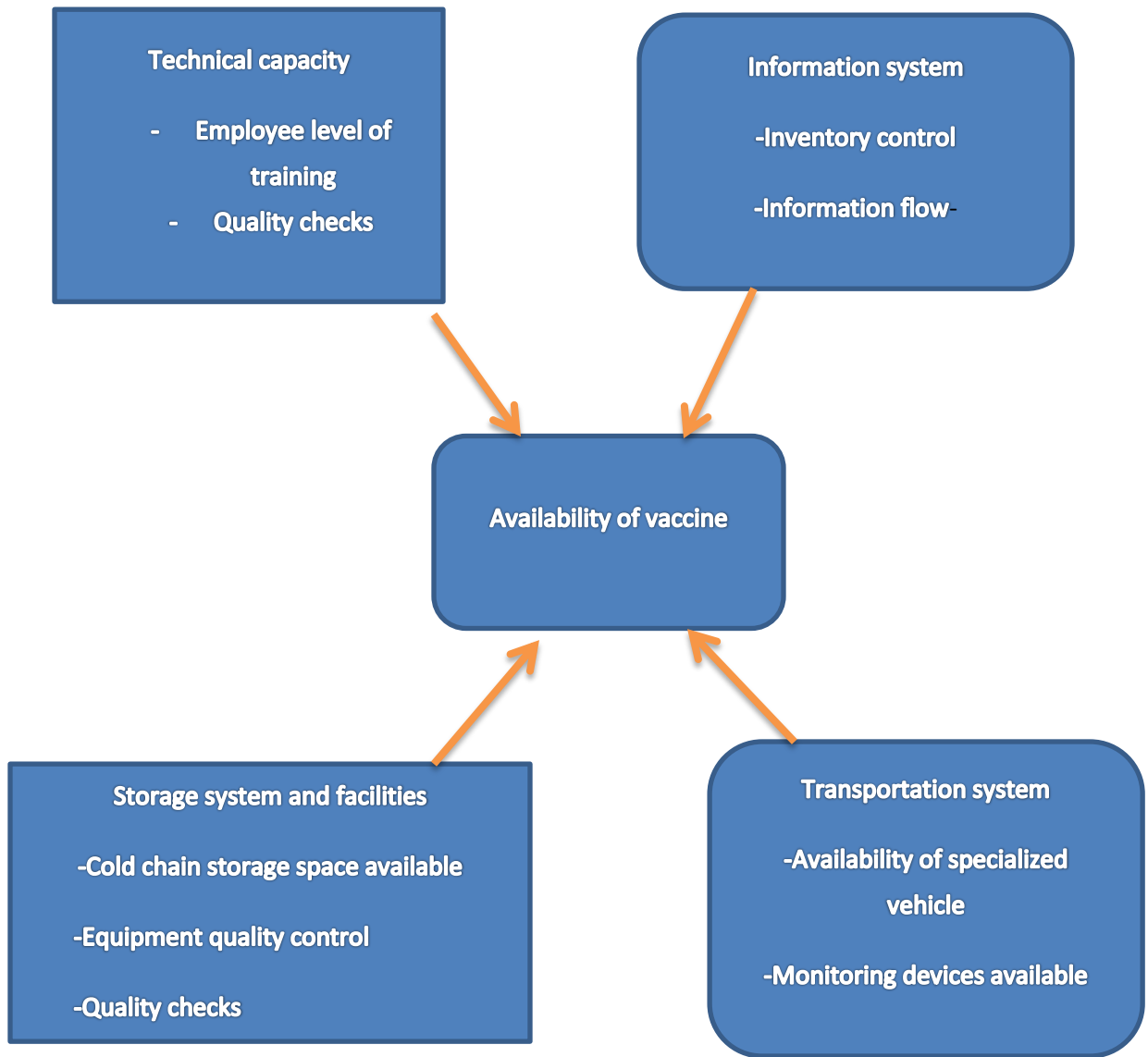


Figure 1: Conceptual framework

Chapter Three: Research Methodology

This chapter describes the procedures that were used in carrying out this research. It deals with the research design, study population, sample size and sampling procedure, data Sources, data type, data collection procedure and analysis.

3.1. Description of study area

The study was conducted in Addis Ababa City which is the capital city of the country. The adjusted total population of Addis Ababa city by 2018 based on 2007 population census is 3,519,849. According to Addis Ababa city administration regional health bureau there are about 53 private facilities providing expanded program for immunization among many private health facilities in the City Administration.

3.2. Research design

The research uses cross sectional survey on the institutions to assess the effect of cold chain management practice on availability of vaccine on private facilities. A study adopted a qualitative methodology with cause and effect study design to answer research questions. This research design is preferred because it seeks to establish casual relationships from sample of people who have been selected to represent a defined population, but without experimental manipulation (Burns R., Burns R., 2008). The data was collected within a short time framework. Hence, it can be considered as a cross-sectional design which was used to collect data on relevant variables.

3.3. Population of the study

Population is defined as the full set of cases from which a sample is taken (Mugenda O., Mugenda A., 2003). The Population of the study is EPI focal person in Private health facilities that provide EPI service under Addis Ababa city administration. According to the information taken from Addis Ababa City Administration there are 53 private health facilities providing expanded immunization program and hence use vaccine. Hence, the populations of the study are those private health facilities legible to provide the service.

3.4. Variables

3.4.1. Independent variables

Now day's increases in number of vaccines have generated serious challenges in their vaccine supply and logistics. People who have been involved in vaccine supply chains over years generally agree that the major challenges facing developing countries like Ethiopia are vaccine storage, Vaccine distribution, technical capacity, and Information management system. These inefficiencies threatens the access, availability and quality of vaccine (Kaufmann J., et al. 2011). In this study thus cold chain management challenges including storage practice, distribution practice, technical capacity and information system are the independent variables. In this case Storage practice refers storage practice at private service delivery point to implement recommended good storage practice and distribution refers to distribution of vaccine to the facility from their supplier (sub city). Technical Capacity refers to human resource adequacy and capability for management of cold chain to meet product nature requirement while information system refers to facilities system of recording, reporting, generating and use data for vaccine logistic decision making.

3.4.2. Dependent variables

The dependent variable in this study is availability of vaccine. Availability refers to availability of adequate stock for the supply period with adequate buffer stock based on agreed inventory management standard operating procedure.

3.5. Sample design

3.5.1. Sampling frame

Mungenda, and Mugenda, (2003) states that a sampling frame is an index of cases from which a sample is collected. In this study the sampling frame for selecting private facilities is the list of total private facilities providing expanded program for immunization obtained from Addis Ababa regional health bureau was used to pick sample from. Selecting the facility is equivalent to selecting EPI focal person as most private facilities have only one focal person.

3.5.2. Sample size

A sample is a representative of a population and sampling facilitates the study of a relatively smaller number of units compared to the target population and therefore helps obtain data that is representative of the whole population (Mugenda O., Mugenda A., 2003). The sample size for this study was calculated using the formula and statistical assumptions presented below which is a single population proportion formula for cross sectional study

$$n = Z_c^2 \times \frac{P \times (1 - P)}{d^2} \times FPC$$

Where:

n = Sample size

Z_c^2 = Confidence level, 1.96 (95% confidence level)

FPC = Finite population correction factor

P = proportion = 50%

d = Margin of error (MOE), 5%

Since there is no current data on effect of cold chain management practice on vaccine availability on private facilities, the technique assumes P=50% in order to maximize the study power given the other parameters. Using the above assumptions it was calculated that a total sample size becomes 47 facilities for the study by applying $n = N * (n / (N + n))$ where N=53.

3.5.3. Sampling technique

After determining sample size, the researcher was used lottery method to draw 47 health facilities from a total of 53 private facilities providing vaccination service under Addis Ababa city administration to use simple random probability method which is usually a preferred with survey based research strategies.

3.6. Data gathering tool, data sources, types and collection procedure

The main instrument for data collection used was a structured questionnaire. A questionnaire is a method of survey data collection with a group of printed questions which are deliberately designed and structured to gather information from respondents (Sushil S., 2010). The questionnaires contained relevant questions which were designed with the objectives of the study in mind. Five point Likert's Scale questionnaire was designed to collect data from vaccine focal

personnel at private health facilities. The Questionnaires was distributed to vaccine focal person with brief explanation of how to fill up on providing tool and quality check up on receipt. The tool consists of demographic information of the respondent (gender, age, education and profession) and cold chain management practices of private health facility including storage, distribution, the technical capacity and the information systems and. Finally, questions about the availability of vaccines in private health facility were included to collect primary data for analysis. With regard to data collection, data collectors were briefed on how to collect data for one day. That is to let the data collectors understand each question in the questionnaire and hence guide them to provide direction during providing data collection tool to the vaccine focal person and also able to check completeness and other possible data quality dimension up on receiving filled questionnaire.

3.7. Reliability and Validity

Testing reliability and validity is to describe on the reliability of measuring tools employed in this research. This is important because reliability shows whether or not an instrument's are free from errors, thus yielding reliable outcomes. The most common technique used in the literature to assess the scale's reliability and stability is use of the cronbach Alpha Statistics, which identifies to what extent items hang together as one set. Low cronbach alpha values mean the items do not capture the same construct, but high values of cronbach alpha indicates the items well measure and reflect the construct. Ideally, cronbach alpha should be over 0.7 to produce reliable scale (Burns and Burns, 2008). Accordingly, internal reliability of a 40 item scale was assessed using the cronbach alpha technique. The scale produced an alpha of 0.952 which indicates very well reliability to capture the construct. The validity of the tool was also checked by conducting pilot study on 5% of the population i.e. two facilities.

3.8. Data analysis

The Data which was obtained from sample facilities analyzed according to objective of the study. In order to ensure logical Completeness and Consistency of responses, data editing and coding were carried out by researcher. Finally, the data was analyzed quantitatively using SPSS version 20 from data obtained through data collection instrument. The researcher analyzed demographic characteristic of participants using frequency, conducted descriptive statistics for

all items of storage, distribution, technical capacity and information system to compute mean and standard deviation. Further to this correlation analysis was conducted to see relationship between variables and finally linear regression analysis was conducted for those independent variables having significant positive relationship with dependent variable. Regression analysis is a statistical method to investigate relationships between more than one independent variables and only one dependent variable. If the independent variable is one, it is simple regression. But, in social Science, it is rare that having only one independent variable (predictor) to predict a social phenomenon (Jihye J., 2015). Hence, the researcher employed standard multiple regression with improved power.

3.9. Ethical considerations

Approval to conduct this study was obtained from Addis Ababa University, School of Commerce Ethical review committee. Discussions were held about the purpose of the study to secure permission from each facility management before starting data collection. In addition verbal consent was obtained from the respondents. Before study participants are requested for consent they were informed in detail about the purpose and procedures of the study, the content of the questioner, its benefit, confidentiality of the information collected from them, the voluntary nature of participation and their right not to respond to questions if they do not want to answer as well as to stop answering and withdraw from the interview at any time

CHAPTER FOUR: Results, Discussion and Interpretation

The Chapter puts survey data in summarized form, discusses and interprets the research findings. The researcher gives interpretation of statistical results from the data. The demographic profile through descriptive statistics, correlation analysis used to show relationship between the variables and the results of multiple regressions will be presented to estimate the value of the dependent variable which is vaccine availability based on independent variables of the study and hypothesis testing will be presented.

4.1 Demographic characteristics

The following six variables indicated in table-1 below were utilized by the study to determine the general characteristics of the respondents of the study. The researcher used frequency statistics to analyze the demographic data as follow.

Table 1: Demographic Characteristics of respondents of the study

Variable	Frequency	Percent
Gender of the respondents		
Male	9	20.9%
Female	34	79.1%
Age of the respondents		
<25 years	6	14%
25-32 years	24	55.85
33-39 years	8	18.6%
40-47 years	1	2.3%
>48 years	4	9.3%
Educational back ground of the respondents		
Certificate	1	2.3
Diploma	20	46.5%
BSc/MSc	21	48.8%
Others	1	2.3%

Experience of the respondents in the job		
<2 years	5	11.6%
2-4 years	9	20.9%
5-7 years	19	44.2%
8-10 years	5	17.6%
>10 years	5	11.6%
Profession of person in charge		
Pharmacist/druggist	2	4.7%
Health officer	6	14%
Nurse/Mid wife	35	81.4%
Number of years in current facility		
1-5 years	28	55.8%
6-10 years	8	18.6%
11-15 years	8	18.6%
>15 years	3	7%
Level of the facility		
Hospital	15	34.9%
Specialty center	12	27.9%
Clinic	15	34.9%
Others	1	2.3%

Source :Survey data (2018)

A total of 47 self-administered questionnaires were distributed to Cold chain focal persons working in sampled private health facilities providing expanded program on immunization and 43 were surveyed with 8.5% accounts for non-respondent and incomplete data which is enough sample size for multiple regression based on the 20 plus 5k (Khamis J., Kepler M., 2010). . Among 47 respondents 20.9%(9) and 79.1%(34) were male and female respectively. With regard to age of the respondents 14%(6), 55.8%(24), 18.6%(8), 2.3%(1), 9.3%(4) of the respondents were in the age category of less than 25 years old, 33-39, 40-47, and greater or equal to 48 years

old respectively. Concerning educational level 2.3%(1), 46.5%(20), 48.8%(21), and 2.3%(1) were certificate, Diploma, BSc/MSc and other (MA) respectively. The respondents' experience in the job were found to be less than 2, 2-4, 5-7, 8-10 and greater than 10 for 11.6%(5), 20.9%(9), 44.2%(19), 11.6%(5) and 11.6%(5) of the respondents' respectively with most of them spent 1-5 years in current facility. The majority of them were nurses/midwife (81.4%) while the remaining 14% and 4.7% were health officers and Pharmacist respectively in terms of profession.

The given 43 respondents were from different institutions with 34.9%(15) being hospital, 27.9%(12) specialty center, 34.9%(15) clinic, and the remaining other. The general characteristics of the respondent and their institution gives the clue that respondents have the necessary understanding and knowledge about subject matter and understand the objective of the study to respond each item in questionnaire.

4.2. Description of effect of Cold Chain Management practices of private health facilities in Addis Ababa City Administration

Respondents were asked to rate the cold chain management practice and availability of vaccine in their institution on a five point likert scale (strongly disagree, disagree, neutral, agree and strongly agree). The mean was computed and utilized with the following assumption: if the mean value is between 0 to 1.5 this implies the respondents strongly disagreed, if the mean value is between 1.5 to 2.5 it implies the respondents' disagreed, if the mean value is between 2.5 to 3.5 it implies the respondents were neutral, if the mean value between 2.5 to 3.5 it implies the respondents were neutral, if the mean value between 3.5 to 4.5 implies the respondents' agreed and a mean value 4.5 and above indicates the respondents' strongly agreed (Burns and Burns, 2008). Accordingly, the mean scores have been computed for all components of the independent variables and the dependent variable by equally weighting the mean scores of all the items under each dimension. The average mean results together with their respective variables was separately presented, analyzed and interpreted as follows.

4.2.1 Storage system

The following table indicates the description of summary of mean and S.D all variables used under storage system obtained from survey data.

Table 2: The mean and standard deviation values from survey data-storage

SN	Variables	N	Mean	S.D
1	Availability of special storage area in the facility	43	3.95	1.272
2	Availability of enough vaccine storage space	43	4.12	1.074
3	The proper stack of vaccine in the refrigerator	43	4.3	1.186
4	Full functionality of storage equipment	43	4.37	1.001
5	The availability of different storage equipment for different vaccine	43	3.77	1.411
6	Storage equipment regularly checked for compliance	43	3.93	1.100
7	The availability of SOP to ensure vaccine proper storage	43	3.83	1.239
8	The availability of temperature monitoring device in use	43	4.19	1.118
9	Temperature record keeping remain between 2-8 degree Celsius during storage	43	4.16	1.153
	Storage System	43	4.067	0.997

Source: Survey data (2018)

Based on the above table the respondents agree on the availability of special storage area for vaccine in private health facilities with mean of 3.95 and S.D of 1.272, Availability of enough vaccine storage with mean of 4.12 and S.D of 1.074, Vaccines are properly stacked in the refrigerators with mean of 4.3 and S.D of 1.186, having fully functional storage equipment with mean of 4.37 and S.D of 1.001, the availability of different storage equipment for different vaccine with mean of 3.77 and S.D of 1.411, having storage equipment regularly checked for compliance with mean of 3.93 and S.D 1.10, the availability of SOP to ensure vaccine proper storage with mean of 3.83 and S.D 1.23, the availability of temperature monitoring device in use with mean 4.19 and S.D 1.118, and temperature record keeping remain between 2-8 degree with mean of 4.16 and S.D 1.153. From the above study result the storage practice in cold chain

management of vaccine in private health facilities providing immunization service is on good status though not excellent.

4.2.2 Distribution system

The following table indicates the mean and standard deviation for all items used to describe distribution system in the study.

Table 3: The mean and standard deviation from Survey data-distribution

SN	Variables	N	Mean	SD
1	Availability of special vehicles for transportation of cold chain items	43	3.37	1.43
2	The availability of enough containers to meet demand for distribution	43	4.12	0.931
3	Use of appropriate mode of transportation	43	4.05	1.05
4	There is temperature monitoring system during transportation	43	3.67	1.229
5	The status of temperature reading during transportation remain from 2-8 degree Celsius	43	3.79	1.206
6	The availability of vaccine collection time table	43	4.23	0.996
7	On time delivery of vaccine as per the schedule	43	3.95	0.999
8	Availability of transport SOP to ensure proper transport condition	43	3.79	1.168
9	Adherence to SOP to ensure proper transport condition	43	3.77	1.151
	Transportation/Distribution system	43	3.86	0.78

Source: Survey data (2018)

From the table-3 above respondents remain neutral on availability of special vehicles for transportation of cold chain items with mean of 3.37 and SD of 1.43. Whereas they agreed on the availability of enough containers to meet demand for distribution with mean 4.12 and SD 0.931, use of appropriate mode of transportation with mean of 4.05 and SD of 1.05, having temperature monitoring system during transportation with mean 3.67 and SD 1.206, Temperature

range from 2-8 degree Celsius during transportation with mean of 3.79 and SD of 1.20, availability of vaccine collection time table with mean of 4.23 and SD of 0.996, on time delivery based on time table with mean of 3.95 and SD of 0.999, availability of transport SOP to ensure proper transport condition with mean 3.79 and SD of 1.16, and adherence to SOP to ensure proper transport condition with mean 3.77 and SD of 1.15. Generally speaking there is good distribution system with significant rooms for improvement.

4.2.3- Technical Capacity

The following table indicates the mean and standard deviation for all items used to describe technical capacity in the study.

Table 4: The mean and standard deviation from survey data-technical capacity

SN	Variables	N	Mean	SD
1	Staff who handle cold chain items are specifically trained	43	4	1.254
2	Provision of enough training for the staff on vaccine distribution system	43	3.33	1.267
3	Availability of enough employees to handle maintenance of equipment	43	3.44	1.419
4	Availability of enough employees to handle the demand	43	3.44	1.221
5	Quality checks to ensure compliance with cold chain supply regulation	43	3.79	1.125
	Technical capacity	43	3.6	1.02

Source: Survey data (2018)

The above table presented technical capacity responses computed for mean and standard deviation. The respondents remained neutral on provision of enough training for the staff on vaccine distribution system (mean=3.33, SD=1.26), availability of enough employees to handle maintenance of equipment (mean=3.44, SD=1.41), availability of enough employees to handle demand (mean=3.44, SD=1.22). But they agreed on Quality checks to ensure compliance with cold chain supply regulation (mean=3.73, SD=0.96). The technical capacity in terms of human resource and equipment is average but not excellent.

4.2.4- Information system

The following table indicates the mean and standard deviation for all items used to describe information system in the study.

Table 5: The mean and Standard deviation values from survey data- information System

SN	Variables	N	Mean	SD
1	Availability of appropriate vaccine forecasting for the facility	43	3.35	1.32
2	Regular consumption report preparation and response	43	4.02	1.185
3	The equality of stock balance and physical count of sample vaccine	43	3.4	1.466
4	Use of vaccine requisition forms for ordering vaccine	43	4.19	1.006
5	Availability of SOP to ensure proper information system	43	3.81	1.18
6	Adherence to SOP to ensure proper information system	43	3.74	1.136
7	Availability of adequate inventory control system in the facility	43	3.65	1.15
8	Preparation and reporting of vaccine wastage and sending to appropriate Organization	43	4.00	1.09
	Information System	43	3.79	0.939

Source: Survey data (2018)

Based on the above result respondents agreed on most of the variables except the equality of stock balance and physical count of sample vaccine (mean=3.4, SD=1.466) and use of vaccine requisition forms for ordering vaccine (mean=4.19, SD=1.006) for which respondents remained neutral. Information system is generally on average but not excellent.

4.2.5- The Availability of vaccine at private Health Facilities in Addis Ababa City Administration

In the following table the summary of availability of vaccine is described based on survey data.

Table 6: The mean and standard deviation for vaccine availability

SN	Variables	N	Mean	SD
1	Availability of adequate quantity of vaccine for the supply period	43	3.81	1.18
2	Availability of adequate buffer stock of vaccine for the supply period	43	3.51	1.31
	Availability	43	3.66	1.19

Source: Survey Data (2018)

As revealed from table 6 respondents agreed on availability of vaccine at private health facilities providing the service. But this service is purely product dependent and availability should be improved to the excellent level to provide quality service through winning public confidence.

4.3. Relationship analysis of Vaccine availability with independent variables of the study

Correlation analysis indicates both the direction and strength of relationship between variables. According to (Burns and Burns, 2008) correlation coefficient ranging from 0.9 to 1 indicates very high correlation, 0.7 to 0.9 indicates high correlation, 0.4 to 0.7 indicates moderate correlation, 0.2 to 0.4 indicates low correlation and 0.0 to 0.2 slight correlations. The direction is determined by the sign of correlation coefficient. Based on this a set of Pearson correlations were computed to determine for existence of relationship. Hence, the researcher utilized this rule for interpretation in the following table.

Table 7: Correlation between variables (within independent variables and between independent and dependent variables)

		Availability
Storage system	Pearson Correlation	.655**
	Sig. (2-tailed)	.000
	N	43
Distribution System	Pearson Correlation	.460**
	Sig. (2-tailed)	.002
Technical capacity	Pearson Correlation	.547**
	Sig. (2-tailed)	.000
Information system	Pearson Correlation	.621**
	Sig. (2-tailed)	.000
Availability		43
	Pearson Correlation	1
	Sig. (2-tailed)	

Source: Survey data (2018)

Table 7 indicates relationship between study variables. From the result presented above there is no very high and high correlation between any pair that assumed correlation coefficient from 0.9 to 1 and 0.7 to 0.9 respectively. But there exists moderate correlation between independent variables and dependent variable. The moderate correlation exist between availability of vaccine and storage system with value of correlation coefficient 0.655 at 0.01 significance level, between availability of vaccine and Distribution system with the value of correlation coefficient 0.46 at 0.01 significant level, between availability of vaccine and technical capacity with the value of correlation coefficient 0.547 at 0.01 significance level, between information system and availability of vaccine with the value of correlation coefficient of 0.621 at 0.01 significance level. All the above correlations are positive correlation (Appendix 3).

4.4. The effects of cold chain management practices on availability of vaccine in private Health Facilities in AA City Administration

Regression analysis was conducted between vaccine availability as dependent variable and storage System, Distribution System, Technical Capacity, and Information System as independent variable to show the effect of cold Chain management practices on the availability of vaccine

Table 8: Model Summary of availability of vaccine

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.703 ^a	.494	.441	.89623

a. Predictors: (Constant), Information system, Distribution System, Storage system, Technical capacity

Source: Survey Data (2018)

Table 9: ANOVA result

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	29.838	4	7.459	9.287	.000 ^b
	Residual	30.522	38	.803		
	Total	60.360	42			

a. Dependent Variable: Availability

b. Predictors: (Constant), Information system, Distribution System, Storage System, Technical Capacity

Source: Survey Data (2018)

Table 10: Coefficient of availability

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	-.134	.767		-.174	.863
Storage system	.512	.220	.426	2.321	.026
Distribution System	.012	.270	.008	.045	.964
Technical Capacity	.009	.245	.008	.038	.970
Information System	.433	.213	.334	2.034	.049

a. Dependent Variable: Availability

Source: Survey Data (2018)

A standard multiple regression was performed between availability of vaccine for supply period as dependent variable and storage system, distribution system, technical capacity and information system as independent variables. The adjusted R squared was significantly different from zero ($F=9.287$, $p<0.001$) and hence 44.1% variation in vaccine availability can be explained by the set of Storage System, Distribution System, Technical capacity and Information System. As indicated above storage system and information system uniquely and significantly contribute to the prediction of vaccine availability namely Storage System ($t=2.321$, $p=0.026$), and Information System ($t=2.034$, $p=0.049$). Since the VIF values are much less than 10 multicollinearity is not a problem. On the other hand, tolerance below 0.2 indicates serious problems, but all are above this (Burns and Burns, 2008). It is also possible to see from the graph visualization that the residuals appeared to be randomly scattered around the horizontal line through zero (annex 3). Therefore, the data satisfied the assumption of multicollinearity, normality of residuals and homoscedasticity while no outliers were identified.

Therefore, the objective of the regression in this study is to find such an equation that could be used to find the effect of predictors on dependent variable. The regression equation takes the following form

$$Y = -0.134 + 0.426X_1 + 0.334X_4 + e$$

Where Y= availability of Vaccine, X1= Storage System, X2=Distribution System, X3= Technical Capacity, X4= information System and e= the residual amount.

From the above equation the availability of vaccine when all independent variables in the equation are zero is -0.134. Keeping all other variables at zero, a unit increase in a storage would lead to a 0.426 increase in the availability of vaccine; a unit increase in information system would lead to 0.334 increase in vaccine availability.

4.5. Hypotheses Testing

The researcher tested the hypothesis based on the above regression analysis by using the β value and P values as follow.

Table 11: Hypothesis testing

Hypothesis	Result	Reason
H0: Storage system has no a significantly positive effect on availability of vaccine in the private health facilities providing immunization service in Addis Ababa under city administration of Addis Ababa	H0: Rejected	$\beta=0.426$ $p<0.05$
H0: Distribution system has no a significantly positive effect on availability of vaccine in in private health facilities providing immunization service under city administration of Addis	H0: Accepted	$\beta=0.008$ $p>0.05$
H0: Technical capacity has no a significantly positive effect on availability of vaccine in private health facilities providing immunization service under city administration of Addis Ababa	H0: Accepted	$\beta=0.008$ $P>0.05$
H0: Information system has no a significantly positive effect on availability of vaccine in the private health facilities under city administration of Addis Ababa	H0: Rejected	$\beta=0.334$ $p<0.05$

Source: Survey Data (2018)

From the above table storage system and information system have significant positive effect on availability of vaccine as their p- value found to be less than 0.05 while distribution system and

technical capacity were found insignificant. Hence null hypothesis were rejected for storage system and information system while null hypotheses were accepted for distribution and technical capacity.

4.6 Discussion

Under this the researcher discusses the finding of the study in line with research questions and provides sort of explanation for the result presented above.

To start with storage system, the result above showed that there are rooms for improvement in order to ensure recommended good storage. It shows storage of vaccine in private facilities in Addis Ababa is on good status but not excellent. Excellence comes through working on all variables addressed under storage in the study. Although respondents agree on all items with some variables like availability of storage equipment for different vaccine, development and implementation of SOP are relatively on lower scale in this range. Close control of storage condition should be strict rather than option. Control of storage conditions and temperature is essential in maintaining the quality of cold chain items and in helping to protect patients from sub-standard or ineffective medicines that may result from inadequate storage control (WHO, 2015a).

With regard to the distribution of vaccines there are gaps during distribution. Respondents remain neutral with regard to availability of special vehicle for transportation of cold chain items. Similar study conducted in coast region, Tanzania showed that the main cause of delay in delivery of vaccines to the health centers was shortage or lack of transport to distribute the vaccine. As indicated in similar study lack of reliable transport at district level contributes to shortage of vaccines at health facility level (Makuru M., 2012). Lack of means of transport to transport vaccine carrier to their facilities. This is dangerous as public transport take long time and the temperature in the carrier may change because of the length of the time. Training is a very important constraint which needs to be considered to improve the vaccine distribution plan. People involved in transportation and supply of vaccines need to be trained and have knowledge of cold chain and how to handle breakage of cold chain. Without pre-requisite knowledge of how to handle vaccines being transported can seriously affect the vaccine potency which in turn can result in wastage of vaccines and thus, increase in their price (WHO, 2004b).

In this study the respondents agreed on staff who handle cold chain items specifically trained. But remain neutral with regard to the adequacy of training and availability of enough employee to handle demand. There are similar studies in other countries supporting this result. In Tanzania, a study showed that in the last 3 years of the study majority of respondents were not attended any training on storage, distribution and handling procedure of vaccine (Makuru M., 2012). A study done on cold chain management knowledge and practices in primary health care facilities in Niassa, Mozambique indicated that 60% of the health workers had no pre-service training in Vaccine storage and distribution (De Tmoteo Mavimbe J.C., Bjune G., 2007). According to study done on Pharmaceutical distributors in Nairobi Country 41% of respondents have absolutely no special training in cold chain (Njuguna, M.W., et al, 2015). Another study conducted in central Italy was also consistent with this. Most of the staff responsible for vaccine storage had poor knowledge about maintaining the cold chain and were unaware of recommendations on vaccine storage (Grass M., et al, 1999). The respondents also remained neutral on availability of enough employees to handle maintenance of equipment.

Respondents agreed with most of items of the information system. But they remained neutral on maintaining stock balance through regular recording and use of requisition forms for vaccine ordering. The study conducted on effective vaccine management (EVM) analysis done by WHO in 75 countries revealed that with a few exceptions, information systems are weak at each level in each region. The same study illustrates more than a third of vaccine storage facilities do not monitor vaccine wastage which can be related to recording and reporting (WHO, 2014b).

The study showed that storage system, distribution system, technical capacity and information system were found to have positive moderate correlation with availability of vaccine. But only Storage system and information system were found to have significant positive effect on availability of vaccine in private health facilities providing EPI service with ($\beta=0.426$ and P value <0.05) and ($\beta=0.334$ and p-value < 0.05) respectively. Hence, the researcher rejected the null hypotheses stating storage System has no a significant positive effect on availability of vaccine private health facilities providing immunization service in Addis Ababa city Administration and information System has no a significant positive effect on availability of vaccine private health facilities providing immunization service in Addis Ababa City Administration. Various weaknesses on storage has been underlined from other studies as major

risk factor associated with limited availability of vaccines (Okwo-bele D.J., 2015, WHO, 2014b). Another similar study conducted on public health facilities showed that information system has no significant positive effect on availability of vaccine unlike this study (Tiya B., 2016).

Some key interventions including constant supervision, training of professionals in charge, promoting access to existing guidelines and making available cold chain tools have been identified to reduce these gaps (WHO, 2014c).

CHAPTER FIVE: Summary, Conclusions and Recommendations

This chapter will cover summary of the major findings, conclusion and recommendations

5.1 Summary of the major findings

The researcher aims to look at effect of cold chain management practice on availability of vaccine on private health facilities providing EPI service in Addis Ababa City Administration. Hence focused on storage management system, distribution system, technical capacity and information system through survey data collected from EPI focal person of sampled health facilities.

The demographic characteristics of participants indicates that participants were educated, experienced and has a knowledge about subject matter of the study. Regarding educational level about 98% of participants hold diploma or more and nearly about 90% of the participants have experience of more than 2 years. This has positive implication about the quality of the research in terms of quality data.

The descriptive analysis indicated that participants agreed on availability of storage system, distribution system being neutral on availability of special vehicle for transportation among items under distribution system, technical capacity though remained neutral on (adequacy of training, number of employee to handle demand and equipment regular follow up and preventive maintenance), Information system being neutral on implementing appropriate forecasting and having and implementing standard operating procedure for information system.

The result of correlation analysis indicates that there is high to moderate positive correlation between variables of the study, while regression analysis indicated that the storage system, the distribution system, the technical capacity and the information system have positive effect on availability of vaccine in private health facilities. Hence, the researcher accepted the alternative hypothesis that storage system has significant positive effect on availability of vaccine in private health facilities in Addis Ababa City Administration and information system has significant positive effect on availability of vaccine in private health facilities in Addis Ababa City Administration.

5.2. Concussion

The researcher conducted this study to identify effect of cold chain management practice namely storage management system, distribution system, technical capacity and information system on availability of vaccine in private health facilities.

The responds agreed that the storage system, the distribution system, the technical capacity and the information system with regard to vaccine is on average performance. That means cold chain management system is on average performance which leaves a number of rooms for improvement to render quality service for the public.

The researcher addressed the research hypothesis. It was found that the storage system, the distribution system, the technical capacity and the information system have a combined significant positive effect on availability of vaccine. Hence, improving the storage system, the distribution system, the technical capacity and the information system would lead to improving vaccine availability at private health facility and lifesaving in turn.

5.3- Recommendations

From the major findings of the study, the researcher recommends the following indispensable points for further improvement cold chain management system.

Storage is critical step in vaccine management with significant positive effect on vaccine availability as revealed by the study where appropriate attention should be given by major stakeholders including FMOH, PFSA, AACHB, and Facility management. Hence FMOH and AARHB should provide strong technical support for private health facilities providing EPI service where significant segment of population is served to ensure proper storage. Further to this facility management should take management ownership to fulfill appropriate storage space and implement storage guideline through having SOP and let staff in charge to implement the SOP.

The distribution system of cold chain items should be fulfilled in terms of infrastructure like having adequate and appropriate delivery vehicle (refrigerated truck if possible, adequate cold box) and processes to ensure cold chain is maintained during transition like SOP for distribution.

There are gaps in number and provision of training for staff handling cold chain items in private health facilities. Therefore, AACHB should work with those private health facilities to enforce facilities hire adequate number of staff and should support in capacitating staff working on cold chain management through short term on site and off site trainings. Facility management should buy this idea and support focal person on capacity building. Further to this the management should ensure regular checkup of equipment and take appropriate measure when necessary to avoid break down through having technicians in place and allocating preventive and curative maintenance budget.

The study showed Information system has significant positive effect on availability of vaccine. Strengthening and upgrading the system to electronic system would help to in critical decision making, information exchange, and wastage reduction. Hence, major stake holders FMOH, AACHB, PFSA and others should work closely with private health facilities to implement appropriate vaccine forecasting, having standard operating procedure in place and implementing SOP in place.

5.4 Suggestion for further study

The researcher suggests future similar study with broader scope involving Customs clearance FMOH, PFSA, Sub cities and health facilities. It would also be good to conduct comparative study involving both public and private health facilities with different methodology. A further detail study on establishing the extent to which the identified logistics challenges affect vaccine safety, efficacy, and quality resulting in wastage by using laboratory test through sampling from known batches of cold chain Pharmaceuticals with evidences and documentation that it has been distributed along the supply chain for traceability and subjected to laboratory analysis.

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Appendix 1: Consent form

ADDIS ABABA UNIVERSITY SCHOOL OF COMMERCE DEPARTMENT OF LOGISTICS
AND SUPPLY CHAIN MANAGEMENT

Thank you in advance

My name is Benti Firomsa. I am conducting a study on the effect of cold chain management practices on availability of cold chain management in private health facilities in Addis Ababa city administration for the partial fulfillment of master's degree in logistics and supply chain management in Addis Ababa University, School of commerce. The information that will be collected for this research project will be kept confidential. Taking part in this study you will contribute towards alleviating the problem of poor vaccines vaccine management and availability. Should you have any query you can contact the researcher at any time

Benti Firomsa: Addis Ababa University

Tel: +251911094249

Email: efiromsa@gmail.com

Name

Signature

Date

Appendix 2: Questionnaire

Questionnaire on effect of cold chain distribution system on availability of vaccine

Part 1: Demographic characteristics of respondents

The general attributes of respondents (i.e. you) are given below. Please select the number that exactly expresses you.

1. Gender:
 - a. Male b. Female
2. Age:
 - a. <25 yrs c. 33-39 yrs
 - b. 25-32 yrs d. 40-47 yrs e. > 48 yrs
3. Educational background:
 - a. Certificate b. Diploma c. BA/Bsc d. MA/Msc e. Other Specify.....
4. Experience in the job:
 - a. <2 yrs b. 2-4 yrs c. 5-7 yrs d. 8-10 yrs e. >10 yrs
5. Professional of in-charge of facility cold chain
 - a. Pharmacist b. Health officer c. Nurse/mid wife d. druggist e. other(specify)
6. How many years have you been employed in this health Facility?
 - a. 1-5 yrs b. 6-10 yrs c. 11-15 yrs d. over 15 yrs
7. Level of your health facility
 - a. Hospital b. Specialty center c. Clinic d. others

Part 2: Vaccine distribution system

Rate to what extent you agree on the following vaccine distribution system components are applicable to your organization. The scale below will be applicable: 1- Strongly disagree 2- Disagree 3- Neither agree nor disagree 4- Agree 5- Strongly agree

No	Storage system and facility	1	2	3	4	5
1	Special storage area available for vaccines in the facility					
2	There is enough vaccine storage space					
3	The vaccines are stacked properly inside the refrigerator					
4	Storage equipment are fully functional					
5	There is different storage equipment for different kinds of vaccines					
6	Storage equipment are regularly checked for compliance					
7	SOPs are available to ensure proper vaccine storage					
8	There is any type of temperature monitoring devices in use					
9	Temperature records readings remains between 2-8 °C					
No	Transportation system					
1	There are special vehicles for transportation of cold chain items					
2	There are enough containers to meet demand for distribution					
3	Appropriate mode of transportation is used					
4	There is temperature monitoring system during transportation					
5	Temperature readings remain between 2-8°C during transportation					
6	Vaccine collection schedule time table is available					
7	Delivery is done within recommended timelines					
8	SOPs are available to ensure proper transport conditions					
9	SOPs are followed to ensure proper transport conditions					
No	Technical capacity					
1	Staffs who handle cold chain items are specifically trained					
2	Enough training provided for the staff on vaccine distribution system					
3	There are enough employees to handle maintenance of equipment					
4	Enough employees to handle the demand					
5	Quality checks are done to ensure compliance with cold chain supply regulations					
No	Information system					
1	The facility has proper vaccine forecasting					

2	Consumption reports are regularly prepared and responded to the appropriate organization					
3	Vaccine stock balance and physical count of sample vaccine are equal					
4	Vaccine requisition forms are used for ordering vaccine					
5	SOPs are available to ensure proper information system					
6	SOPs are followed to ensure proper Information system					
7	There is adequate inventory control system in the health facility					
8	Vaccine wastage reports are regularly prepared and reported to the appropriate organization					

Part 3: Availability of vaccine

No	Availability of vaccine	1	2	3	4	5
1	There is adequate quantity of vaccine for the supply period					
2	There is adequate buffer stock of vaccine for the supply period					

Appendix 3- Data output
Regression

Variables Entered/Removed^a

Mode	Variables Entered	Variables Removed	Method
1	Informations system, DistributionS ystem, Storagesyste m, Technicalcap acity ^b		Enter

a. Dependent Variable: Availability

b. All requested variables entered.

Model Summary^b

Mode	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.703 ^a	.494	.441	.89623

a. Predictors: (Constant), Information system, Distribution System, Storage system, Technical capacity

b. Dependent Variable: Availability

ANOVA^a

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	29.838	4	7.459	9.287	.000 ^b
	Residual	30.522	38	.803		
	Total	60.360	42			

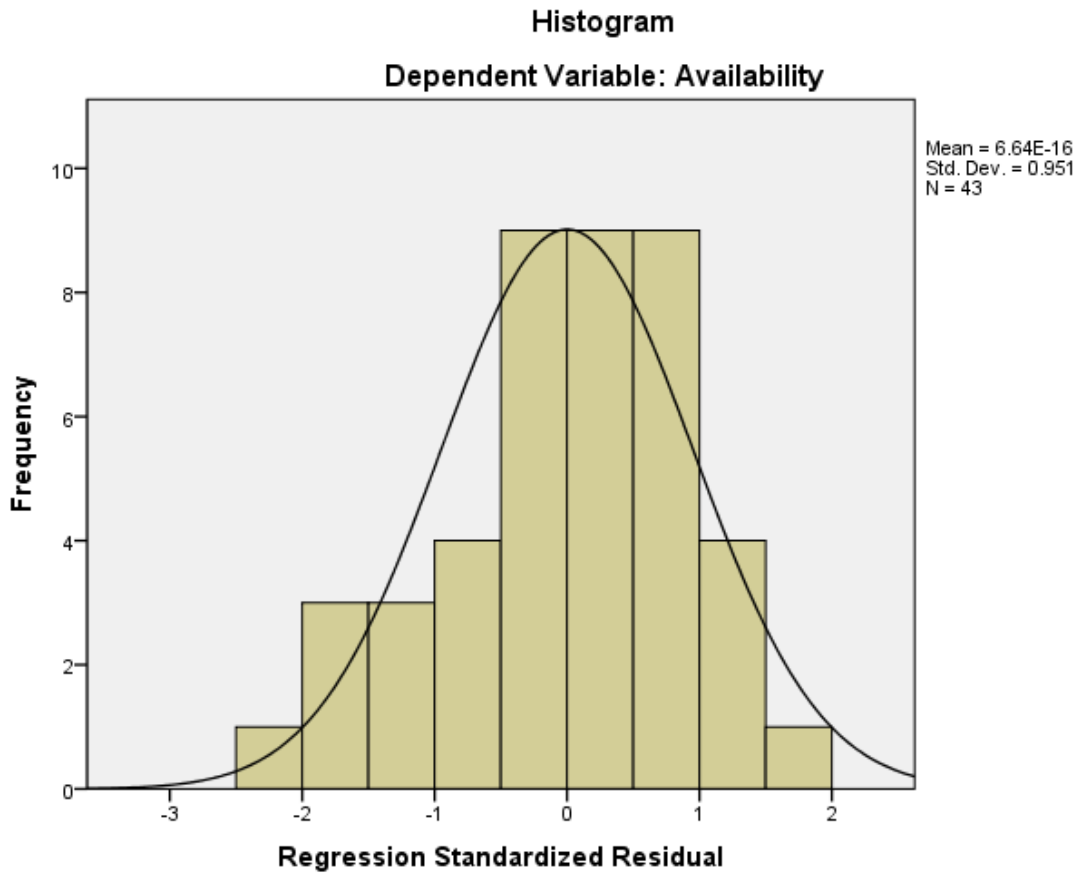
a. Dependent Variable: Availability

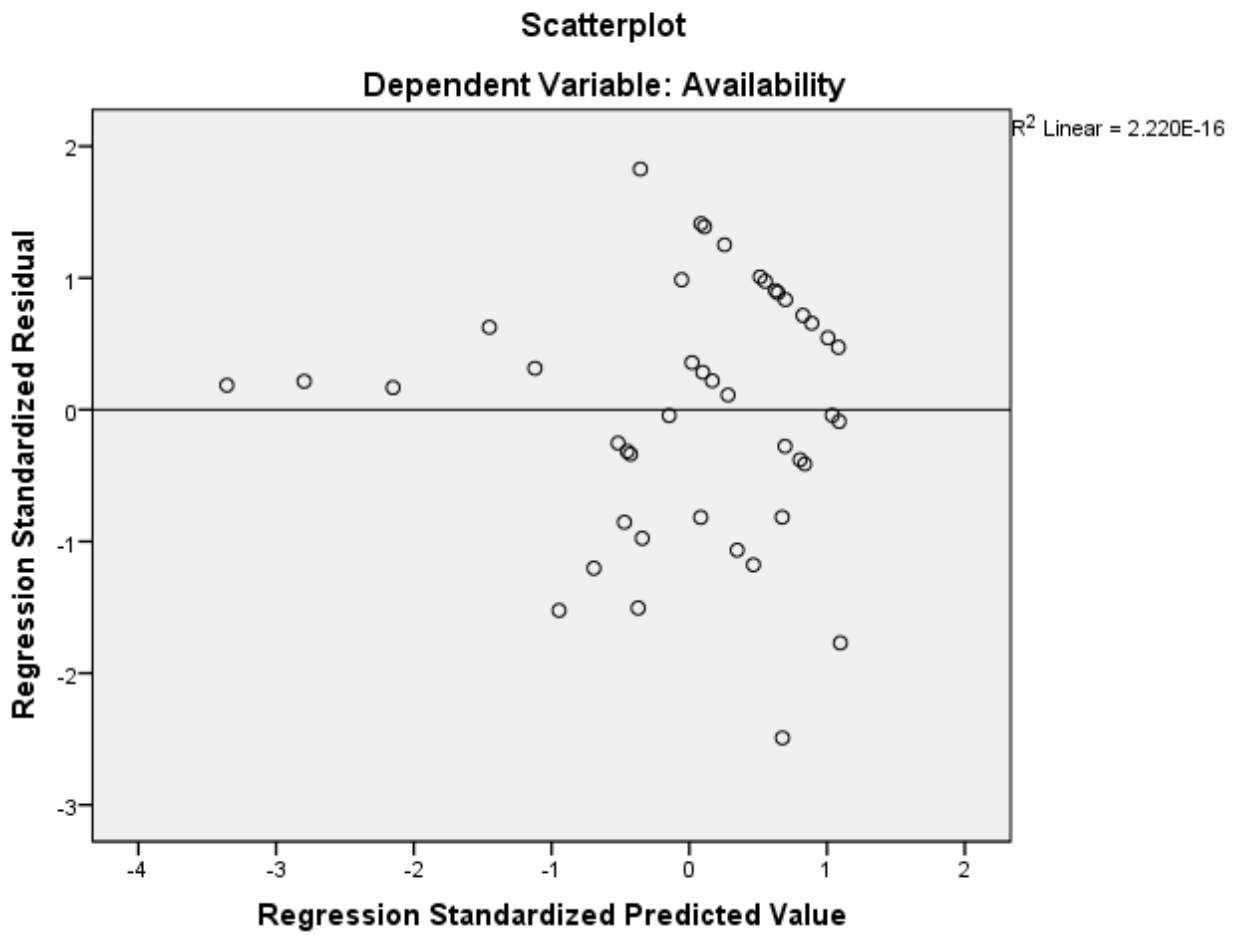
b. Predictors: (Constant), Information system, Distribution System,
Storage system, Technical capacity

Collinearity Diagnostics^a

Model	Dimension	Eigenvalue	Condition Index	Variance Proportions				
				(Constant)	Storage system	Distribution System	Technical capacity	Information system
1	1	4.908	1.000	.00	.00	.00	.00	.00
	2	.039	11.166	.51	.02	.00	.16	.01
	3	.025	14.073	.00	.00	.17	.08	.72
	4	.017	16.952	.01	.96	.02	.21	.10
	5	.011	21.545	.48	.01	.81	.54	.17

a. Dependent Variable: Availability





Reliability Statistics

Cronbach's Alpha	N of Items
.952	40